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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

IN RE PACIFIC FERTILITY CENTER
LITIGATION

This Document Relates to:
No. 3:18-cv-01586
(A.B., C.D., E.F., G.H., and I.J.)

Master Case No. 3:18-cv-01586-JSC

**PLAINTIFFS' MOTION IN LIMINE NO. 4:
INFORMED CONSENT FORMS**

Pretrial Hearing: April 29, 2021
Time: 2:00 p.m.
Judge: Hon. Jacqueline S. Corley
Place: Courtroom F, 15th Floor

Trial Date: May 20, 2021

INTRODUCTION

Before Plaintiffs received fertility services from the Pacific Fertility Clinic (PFC), they were required to sign informed consent forms. Defendant Chart has previously argued that PFC's informed consent forms fully apprised Plaintiffs they could lose their eggs and embryos if the lab's storage equipment were to fail. At the time, Plaintiffs were pursuing a failure-to-warn claim against Chart and so Plaintiffs' understanding of the risks associated with storing frozen eggs and embryos was potentially relevant. Plaintiffs have since dropped their failure-to-warn claim, but Chart has not dropped the informed consent forms from its exhibit list. Because Plaintiffs' knowledge is no longer at issue and the language in the informed consent forms has the potential to confuse or mislead jurors, Plaintiffs respectfully request that the Court exclude the forms from evidence and preclude Chart from asking Plaintiffs or PFC about them.

BACKGROUND

Trial Exhibits 291, 295, 305, 309, 314, 315, 316, 317, 318 are the informed consent forms executed by Plaintiffs before undergoing fertility treatment at PFC. The forms include over twenty pages of legal disclosures regarding the medical procedures Plaintiffs were about to undergo, along with the risks and benefits of those medical procedures. Among the many theoretical risks disclosed to Plaintiffs were risks about laboratory equipment potentially failing. For instance, page 8 of Plaintiff G.H.'s informed consent form includes the following list of potential adverse events that could prevent a pregnancy despite the exercise of reasonable precaution:

In spite of reasonable precautions, any of the following may occur in the lab that would prevent the establishment of a pregnancy:

- Fertilization of the egg(s) may fail to occur.
- One or more eggs may be fertilized abnormally resulting in an abnormal number of chromosomes in the embryo; these abnormal embryos will not be transferred and will be discarded.
- The fertilized eggs may degenerate before dividing into embryos, or adequate embryonic development may fail to occur.
- Bacterial contamination or a laboratory accident may result in loss or damage to some or all of the eggs or embryos.
- Laboratory equipment may fail, and/or extended power losses can occur which could lead to the destruction of eggs, sperm and embryos.
- Other unforeseen circumstances may prevent any step of the procedure to be performed or prevent the establishment of a pregnancy.
- Hurricanes, floods, earthquakes or other 'acts of God' (including bombings or other terrorist acts) could destroy the laboratory or its contents, including any sperm, eggs, or embryos being stored there.

(Trial Ex. 305 at 8.)

On page 18 of the same form, the possibility that the lab’s freezing equipment or storage systems could fail was similarly disclosed to Plaintiff G.H.:

In any technical process that requires mechanical support, failure of equipment can occur. Freezing equipment can fail, electrical power systems can fail, lighting systems and temperature and gas control systems can fail at critical stages of the procedure, storage systems can crack or leak liquid nitrogen, and technical errors can occur. Liquid nitrogen storage can cause rupture of a storage system with loss of stored eggs. Back-up systems and staff training decrease the likelihood of any malfunction, but unforeseen situations can occur that risk loss or damage to cryopreserved eggs.

Chart referenced this language earlier in the case, citing it repeatedly in support of its request to dismiss Plaintiffs’ failure to warn claim. (*See* 6/4/19 Mot. at 1, 3, 5-7, ECF No. 229; 7/16/19 Reply at 1, 2-4, ECF No. 252.) Chart urged dismissal because “[s]trict liability for failure to warn simply does not attach where, as here, the alleged dangerous propensity is ‘known to the injured person at the time the product is used.’” (6/4/19 Mot. at 6 (quoting *Salyards v. Metso Minerals Tamper OY*, 2005 WL 3021959, at *9 (E.D. Cal. Nov. 10, 2005).) “As plainly evident in their Informed Consent Agreements,” Chart argued, “Plaintiffs each knew of the purported risks on which they base their failure to warn claim.” (*Id.*) Chart said it had relied on PFC to convey appropriate warnings to its customers, PFC had done so, and under the sophisticated-intermediary defense, Chart could not be held liable for failing to warn Plaintiffs about the risks associated with using one of its cryogenic storage tanks. (6/4/19 Mot. at 1, 7; 7/16/19 Reply at 1, 5-6.)

ARGUMENT

If Plaintiffs were still pursuing a failure-to-warn claim, the informed consent forms Plaintiffs signed before undergoing fertility treatments might well be relevant and admissible. A failure-to-warn claim would require Plaintiffs to prove they were unaware of the risks of using Chart’s cryogenic storage tank and that they had not been warned by Chart or PFC about those risks. *See* CACI No. 1205. Chart could then introduce evidence that Plaintiffs signed informed consent forms to suggest that Plaintiffs had already been warned by a sophisticated intermediary and so no further warning was necessary. *See Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 188 (2016) (“the seller is not required to give actual warnings telling the buyer what it already knows”).

1 Plaintiffs are no longer pursuing failure-to-warn claims, however, and so whether Plaintiffs
 2 were adequately warned of the risks associated with storing their eggs and embryos in Chart's
 3 cryogenic storage tanks is no longer relevant. Even if Chart could show that Plaintiffs were
 4 sophisticated users who understood the risks of using cryogenic storage tanks, that would not provide a
 5 defense to Plaintiffs' claims that Chart's defective design and manufacture of this particular cryogenic
 6 tank caused damage to their eggs and embryos. *See Johnson v. Honeywell Internat. Inc.*, 179 Cal. App.
 7 4th 549, 559 (2009) (sophisticated user defense does not apply to design defects); CACI No. 1244
 8 (sophisticated user defense given only for failure-to-warn cases). Nor would it be a defense if Chart
 9 could show that PFC was a sophisticated intermediary that Chart reasonably relied on to warn Plaintiffs
 10 about the dangers associated with its cryogenic storage tanks. *See Webb*, 63 Cal. 4th at 187 ("Like the
 11 sophisticated user defense, the sophisticated intermediary defense applies to failure to warn claims").

12 Allowing Chart to introduce the informed consent forms into evidence, or to question Plaintiffs
 13 about the information disclosed to them in those forms, would confuse the issues, waste time, and
 14 potentially mislead the jury. Jurors might not appreciate that manufacturers are strictly liable for harm
 15 caused by manufacturing or design defects regardless of any warning that is provided to consumers.
 16 They could believe that Plaintiffs have waived or released their rights by signing the informed consent
 17 forms. And even after they are instructed on the law, jury members are likely to wonder why informed
 18 consent forms were admitted into evidence if they are not relevant to Chart's liability. Plaintiffs
 19 accordingly request that the Court exclude the informed consent forms as irrelevant, or as evidence
 20 whose probative value is substantially outweighed by the danger of confusing the issues, misleading the
 21 jury, or wasting time. *See Fed. R. Evid.* 401, 403.

22 CONCLUSION

23 The lengthy informed consent forms signed by Plaintiffs prior to the March 4th incident may
 24 have been relevant if Plaintiffs were still pursuing failure-to-warn claims. But under the legal theories
 25 that Plaintiffs are presenting to the jury, any warnings contained within those forms no longer bear on
 26 Chart's liability and would only confuse the issues, waste time, and potentially mislead the jury.
 27 Plaintiffs therefore ask that the Court exclude Trial Exhibits 291, 295, 305, 309, 314, 315, 316, 317,
 28

1 and 318 and prohibit Chart from inquiring about any warnings given to Plaintiffs prior to the March 4th
2 incident.

3
4 Dated: April 14, 2021

Respectfully submitted,

5 By: /s/ Amy M. Zeman

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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

IN RE PACIFIC FERTILITY CENTER
LITIGATION

Case No. 3:18-cv-01586-JSC

**DEFENDANT CHART INC.'S
OPPOSITION TO PLAINTIFFS'
MOTION IN LIMINE NO. 4:
INFORMED CONSENT FORMS**

Hearing: April 29, 2021
Time: 2:00 p.m.
Judge: Hon. Jacqueline Scott Corley
Place: Courtroom F, 15th Floor
Trial: May 20, 2021

1 **I. INTRODUCTION**

2 Plaintiffs' motion *in limine* No. 4 seeks to exclude the informed consent forms furnished
 3 by Pacific Fertility Center (PFC) and signed by Plaintiffs. Plaintiffs' argument misapprehends
 4 what is relevant in this case by suggesting the informed consent forms are relevant only if Plaintiffs
 5 had maintained their failure to warn claims. However, these forms are highly relevant to not only
 6 what Plaintiffs knew, but also what PFC knew with respect to the potential failure of tanks at its
 7 facility. Plaintiffs' motion highlights the germane language in the forms that PFC provided and
 8 Plaintiffs agreed to:

- 9 • Laboratory equipment may fail, and/or extended power losses can occur which could
 10 lead to the destruction of eggs, sperm and embryos.
- 11 • In any technical process that requires mechanical support, failure of equipment can
 12 occur. Freezing equipment can fail, electrical power systems can fail...storage systems
 13 can crack or leak liquid nitrogen, and technical errors can occur. Liquid nitrogen
 14 storage can cause rupture of a storage system with loss of stored eggs. Back-up systems
 15 and staff training decrease the likelihood of any malfunction, but unforeseen situations
 16 can occur that risk loss or damage to cryopreserved eggs.

17 (Pls.' MIL No. 4 at 1:20-2:6.)

18 Obviously, PFC and Plaintiffs were aware of the potential risks associate with
 19 cryopreservation of their eggs and embryos, including potential tank failure. While PFC
 20 represented that back-up systems and staff training decreased the risk of egg or embryo loss, with
 21 respect to the Tank 4 incident, its personnel actually removed one of the systems in place to prevent
 22 egg and embryo loss when they unplugged the TEC 3000 controller on Tank 4 and then failed (for
 23 17 days) to contact Chart for a fix. Likewise, Plaintiffs were made aware of, and signed off on,
 24 the inherent risks associated with cryopreservation of their eggs and embryos.

25 The informed consent forms are evidence relevant to two primary issues in this case: (1)
 26 whether PFC's acts and omissions were negligent, even reckless, and their proximate cause of
 27 Plaintiffs' injuries; and (2) whether Plaintiffs' knowledge of the risks of egg and embryo damage
 28 associated with cryopreservation diminish their claims for emotional distress damages. Plaintiffs

are well aware of PFC's role in this case and should not be permitted to blind the jury to that role. Chart is entitled to defend itself with these highly relevant facts and, therefore, Plaintiffs' motion *in limine* No. 4 should be denied.

II. ARGUMENT

Evidence is relevant and admissible if it has any tendency to make a fact more or less probable than it would be without the evidence; and the fact is of consequence in determining the action. Fed. R. Evid. 401 and 402.

1. The informed consent evidence demonstrates PFC knew the risks of tank failure when they unplugged the TEC 3000 controller.

PFC's acts and omissions are central to this case. The informed consent form shows PFC was aware of the potential risks of tank failure, and even made its patients sign the form demonstrating their awareness. It is undisputed that Tank 4 included the TEC 3000 controller (and was intended to maintain its failsafe functionality), which would alert PFC to any potentially dangerous issues with the tank. (Dkt. No. 705-8, Leaphart Expert Report, pp. 9, 23, 35-37; Dkt. No. 669-16, Leaphart Depo., 87:9-88:7.) It is further undisputed that Chart had certain troubleshooting and service procedures in place on February 15, 2018 when PFC unplugged the TEC 3000 controller, rendering it unable to detect any dangerous conditions in Tank 4. (Dkt. No. 705-8, Leaphart Expert Report, pp. 1, 33.) For the next 17 days, instead of contacting Chart to service or fix the controller, PFC's lab director instructed lab workers to plug in the controller once a day to top off the liquid nitrogen in Tank 4 before closing the lab for the day. (Dkt. No. 633-12, October 9, 2019 Conaghan Depo, 90:23-91:4, 93:22-25, 148:25-149:2.)

The role PFC played in any alleged failure of Tank 4 and, ultimately, Plaintiffs' alleged injuries will be a significant issue in front of the jury. PFC unplugging the safety mechanism from Tank 4, despite knowing the risks of tank failure, then keeping it unplugged except during fillings for 17 days without contacting Chart to service the controller, are facts the jury will need to consider in determining PFC's role and responsibility in this case. The informed consent forms contain evidence highly relevant to those facts of consequence to this action. For this reason alone, Plaintiffs' motion *in limine* No. 4 should be denied.

2. **The informed consent evidence demonstrates Plaintiffs knew the risks of tank failure and chose to move forward with cryopreservation, which undermines certain bases of Plaintiffs' emotional distress claims.**

Plaintiffs' emotional distress expert, Dr. Elizabeth Grill, has provided the opinion that the five plaintiffs, A.B., C.D., E.F., G.H., and I.J., experienced emotional distress damages as a result of the Tank 4 failure. Part of her emotional distress opinion is based on literature. At deposition, Dr. Grill testified :

Q: Do you believe that emotional distress, pain, suffering, grief, anxiety, uncertainty, loss, shock, depression, and feelings of being out of control would be expected for individuals who cryopreserved materials that had been potentially compromised?

A: Based on the literature of perinatal loss and embryo disposition and my clinical judgment, yes, I would say that a traumatic event like losing their material that they had spent so much time investing in, would create that kind of a traumatic reaction.

(Dkt. No. 633-6, Grill Depo., 50:2-11.) In her report, Dr. Grill references the literature, stating:

Given the high expectation for successful treatment with modern medicine, and the concomitant anxiety and distress when a treatment cycle fails, nearly half of those who initiate treatment drop out after their first meeting due to stress and fear about the process, among other things.

(Dkt. No. 633-6, Grill Expert Report, p. 12, Section IV(2)(a)(2) (emphasis added).) For each plaintiff, Dr. Grill provides the same basic premise upon which she grounds her opinion that the Tank 4 failure caused emotional distress to that plaintiff. For example, she writes:

- Cryopreservation and freezer storage services are sold as an "insurance policy" that allows women the freedom to defer having children until they find the right partner, finish their education or pursue careers that could in turn **provide peace of mind**. [Plaintiff's name] believed the storage of her eggs provided her such an insurance policy.
- Loss of or damage to those eggs—**or even the mere possibility of loss or damage—can be traumatic for the person whose eggs are (or were) frozen.** [Plaintiff's name] experienced trauma as a result of the Tank Incident.

(See e.g., Dkt. No. 633-6, Grill Expert Report, p. 20, Section V(1)(2)(a) and (b)) (emphasis added.)

Dr. Grill then utilizes the plaintiffs' depositions and interviews to explain the source of emotional distress for each. For example, when explaining the basis of plaintiff I.J.'s emotional distress claim, she states:

[I.J.] remembered feeling filled with “anger” and said that when she read the email, she felt “shock and disbelief” and asked, “Why me? Why my tank?” [] She felt shock, distress, confusion, grief, anxiety, and loss. As she stated in her deposition, “they had a product that was not up to code, up to standard, and it was sent out and used to store my eggs, and it failed.”

(Dkt. No. 633-6, Grill Expert Report, p. 25, Section V(2)(f).)

One significant issue with Dr. Grill’s opinion is that it is based on the notion that Plaintiffs’ experienced shock and disbelief that the tank at PFC failed. Indeed, she infers Plaintiffs’ purported emotional reaction to the news of the Tank 4 failure occurred, at least in part, because “even the mere possibility of loss or damage” of eggs or embryos can be traumatic. But the “mere possibility” of loss or damage to their eggs or embryos existed at the time each Plaintiff signed the informed consent—*i.e.*, at the time they chose to move forward with the cryopreservation process, they knew of the mere possibility of equipment failure and embryo damage. These facts chip at the weight of Dr. Grill’s emotional distress opinions and, consequently, Plaintiffs’ claims for emotional distress damages. The informed consent forms are clear evidence relevant to those facts.

3. Introduction of the informed consent forms will not confuse the issues or mislead the jury.

As discussed, the informed consent forms are relevant to at least two important issues in this case. Exclusion of these forms will only serve to unfairly prejudice Chart. Plaintiffs’ claim this evidence should be excluded under Fed. R. Evid. 403 because it would confuse the issues or mislead the jury is baseless. First, part of Plaintiffs’ argument for exclusion is based on the flawed premise that “jury members are likely to wonder why informed consent forms were admitted into evidence if they are not relevant to Chart’s liability.” (Plaintiffs’ Motion *In Limine* No. 4, 3:15-16.) However, as explained above, the forms are relevant to PFC’s liability. Further, there is no risk of misleading or confusing the jury because the Court could easily instruct as to which issues the forms are or are not relevant. Moreover, the Court could easily, if necessary, instruct the jury that these forms did not waive or release Plaintiffs’ rights. Any Rule 403 concerns Plaintiffs’ have can be mitigated by an instruction. *See StarStone Nat’l Ins. Co. v. Indep. Cities Risk Mgmt. Auth.*, No. CV 19-1130 PA (EX), 2020 WL 6143608, at *4 (C.D. Cal. Aug. 19, 2020) (finding a “properly

1 written limiting instruction may also resolve [a party's] Federal Rule of Evidence 403 prejudice
2 concerns.").

3 At bottom, the only risk of unfair prejudice would be to Chart if the Court were to exclude
4 the informed consent form evidence, which is relevant to (1) PFC's knowledge and responsibility
5 in this case; and (2) Plaintiffs' claims for emotional distress damages resulting from the Tank 4
6 failure at PFC. Plaintiffs' motion *in limine* No. 4 should be denied.

7 **III. CONCLUSION**

8 WHEREFORE, Defendant Chart, Inc. respectfully requests this Honorable Court to deny
9 Plaintiffs' request to exclude informed consent forms, and for any other relief this Honorable Court
10 may deem equitable and just.

11 Dated: April 15, 2021

Respectfully submitted,

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